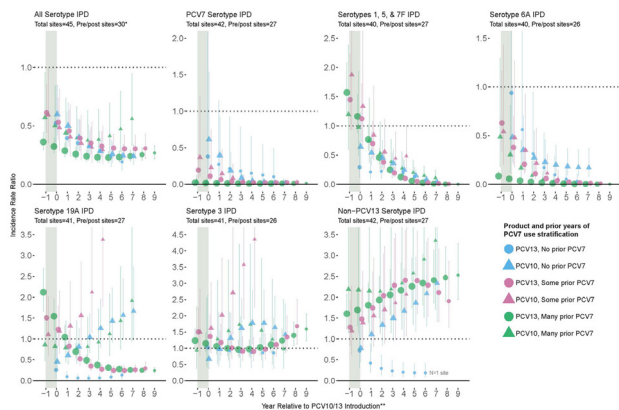


vaccine-type (VT), non-VT type and all-serotype (ST) IPD incidence following introduction of PCV10/13 among children < 5 years of age.

**Methods.** IPD ST-specific incidence or cases and population denominators were obtained directly from surveillance sites. IPD incidence rate ratios (IRRs) for each site were estimated comparing the pre-any PCV incidence to each post-PCV10/13 year using Bayesian multi-level, mixed effects Poisson regressions. All-site weighted average IRRs were estimated using linear mixed-effects regressions. Results were stratified by product (PCV10 vs. PCV13) and years of prior PCV7 use (none, some [1-3 years or 4-5 years if < 70% PCV uptake], or many [ $\geq$  4 years with  $\geq$  70% uptake]).

**Results.** Analyses included 45 surveillance sites from 31 countries, primarily high-income (80%). Thirty surveillance sites had pre- and post-PCV data (PCV10: no prior PCV7=5 sites, some=2, many=2; PCV13: no prior PCV7=3, some=5, many=13). Five years after PCV10/13 introduction, the all-site IRRs in children < 5 years were generally similar across products and prior PCV7 use strata for all-serotype IPD (range 0.23-0.41), PCV7 STs (0.01-0.13), PCV10non7 STs (1, 5, and 7F; 0.05-0.20), and ST6A (0.01-0.18). IRRs for ST19A were lower for PCV13 sites (range by PCV7 use: 0.09-0.31) than for PCV10 sites (1.1-1.4). ST3 IRRs were dynamic, differing by product at year 5 (range for PCV13 sites=0.86-1.02; PCV10 sites=1.55-1.78), but converging by year 7. NonPCV13 STs increased across all strata (range 1.9-2.6), except one strata with a single African site that declined.

Figure 1. All-Site Weighted Average Incidence Rate Ratios, Children <5>



\* Total sites indicates number of sites with incidence rate data included and pre/post sites indicates number of sites with both pre- and post-PCV data to estimate IRRs for each outcome. \*\* Year 0 indicates the year of PCV10/13 introduction and year -1 indicates the last year of PCV7 use prior to PCV10/13 introduction.

**Conclusion.** All-serotype IPD in children < 5 years declined following both PCV10 and PCV13 use, driven by substantial declines in VT serotypes and offset by increases in nonPCV13 STs. ST19A decreased among PCV13-sites, mitigating replacement disease occurring after PCV7 use, but increased, on average, among PCV10-sites. Changes in ST3 were heterogeneous, increasing in some sites and no change from baseline in others. Data from low-income and high-burden settings were limited.

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#### 1174. Phase 3 Study to Evaluate the Safety, Tolerability, and Immunogenicity of Catch-up Vaccination Regimens of V114 in Healthy Infants, Children, and Adolescents (PNEU-PLAN)

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**Session:** P-69. Pediatric Vaccines

**Background.** Despite widespread use of pneumococcal conjugate vaccines (PCVs) in children, morbidity and mortality caused by pneumococcal disease (PD) remain high, in part due to the emergence of disease caused by non-vaccine serotypes (STs). In addition, many children do not receive the recommended number of PCVs on schedule and, therefore, are at risk for PD. V114 is an investigational 15-valent PCV that contains two epidemiologically important STs, 22F and 33F, in addition to the 13 STs present in the licensed 13-valent PCV (PCV13; Prevnar 13<sup>®</sup>). This Phase 3 descriptive study evaluated the safety and immunogenicity of V114 and PCV13 when given as catch-up vaccination in children who are pneumococcal vaccine-naïve or previously immunized with lower valency PCVs.

**Methods.** Solicited adverse events (AEs) were collected for 14 days after each vaccination. Serious adverse events (SAEs) were collected throughout study participation.

Immunogenicity was evaluated by anti-pneumococcal polysaccharide ST-specific immunoglobulin G (IgG) geometric mean concentrations (GMCs) at 30 days post-last vaccination.

**Results.** 606 healthy children, aged 7 months through 17 years, were randomized (double-blind) to receive V114 (n=303) or PCV13 (n=303) via age-appropriate catch-up vaccination schedules (Table 1). V114 had an acceptable safety profile and was well tolerated. Similar proportions of children aged 7–11 months and 2–17 years reported AEs in the V114 and PCV13 groups. A larger proportion of children aged 12–23 months reported AEs in the V114 group (79%) than the PCV13 group (59%). The proportion of children who reported SAEs was comparable among vaccination groups (V114 and PCV13, respectively, 7–11 months: 10.9%, 7.8%; 12–23 months: 6.5%, 6.3%; 2–17 years: 2.3%, 2.3%). No SAEs were reported to be vaccine-related, and no deaths occurred. At 30 days after the last PCV dose, ST-specific IgG GMCs were comparable for the 13 shared STs and were higher in the V114 group for 22F and 33F.

Table 1. Catch-up vaccination schedules in V114-024

Age at randomization	PCV status	V114/PCV13 dose schedule
7–11 months (n=128)	Naïve	Dose 1: At randomization
		Dose 2: 4–8 weeks after Dose 1
12–23 months (n=126)	Naïve	Dose 1: At randomization
		Dose 2: 8–12 weeks after Dose 1
2–17 years (n=352)	Partial regimen of PCV7 (Prevnar <sup>®</sup> ), PCV10 (Synflorix <sup>™</sup> ), or PCV13	Dose 1: At randomization <sup>†</sup>
	Complete regimen of PCV7 or PCV10	

<sup>†</sup>Dose given to children  $\geq$ 12 months of age.

<sup>‡</sup>At least 8 weeks after previous dose of PCV.

n=number of children randomized to individual age cohort.

PCV, pneumococcal conjugate vaccine; PCV7, 7-valent pneumococcal conjugate vaccine; PCV10, 10-valent pneumococcal conjugate vaccine; PCV13, 13-valent pneumococcal conjugate vaccine.

**Conclusion.** Catch-up vaccination with V114 in healthy children aged 7 months through 17 years had an acceptable safety profile, was well tolerated, and provided comparable immune responses to the 13 serotypes shared with PCV13, and higher immune responses to serotypes 22F and 33F.

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#### 1175. Influenza Vaccine Hesitancy in Hospitalized Children, Before and During the COVID-19 Pandemic

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**Session:** P-69. Pediatric Vaccines

**Background.** Influenza vaccine is recommended for all children  $\geq$ 6 months, yet uptake is suboptimal. We aimed to quantify child influenza vaccine coverage and identify factors associated with influenza vaccine hesitancy (VH) before and during the COVID-19 pandemic.

**Methods.** We conducted a prospective, repeated cross-sectional assessment in English and Spanish of caregiver influenza knowledge, attitudes, behaviors, and associated VH among hospitalized children 6 months through 18 years at a large pediatric medical institution. Caregivers were enrolled 4–5 days per week, between 12/11/2019–1/31/2020 and 12/8/2020–4/5/2021. VH was assessed using the Parent Attitudes about Childhood Vaccines (PACV) survey; PACV score  $\geq$ 50 denoted VH. Descriptive statistics and multivariable logistic regression were used.

**Results.** During 2019–2020 and 2020–2021 influenza seasons, 269/282 (95%) and 295/307 (96%) of approached caregivers enrolled, respectively. By caregiver report,